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STATE PASS USTR-JJENSEN
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SYDNEY FOR CS

E.O. 12958: N/A
TAGS: ETRD ECON NZ
SUBJECT: INDUSTRY SEES HIGHER COSTS UNDER NEW ZEALAND-AUSTRALIA REGULATORY AGENCY

REF: (A) 05 WELLINGTON 119; (B) 04 WELLINGTON 596

¶1. (SBU) Begin summary: Proposed rules for a new Australian-New Zealand regulatory agency for therapeutic products will make it costlier for U.S. makers of medical devices and complementary medicines to operate in New Zealand, according to the manufacturers' representatives. They contend the proposed rules, issued May 23, would drive many of their products out of New Zealand. In contrast, the pharmaceutical industry expects the agency would expedite the process for obtaining marketing approval for medicines and would save the industry in regulatory costs. Its support of the agency, however, hinges on the New Zealand government continuing to allow direct-to-consumer advertising of prescription drugs, which is not allowed in Australia. Meanwhile, the government does not yet have enough political support to pass the legislation necessary to set up the agency. End summary.

¶2. (U) Australia and New Zealand signed an agreement in December 2003 to provide unified regulation of prescription pharmaceuticals as well as therapeutic goods that have been virtually unregulated in New Zealand, including medical devices, over-the-counter medicines, dietary and nutritional supplements, and cosmetics and toiletries (ref B). The proposed agency -- the Australia New Zealand Therapeutic Products Authority -- would replace the Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). The deadline for public submissions on the draft rules is August 15. The New Zealand government is hoping to introduce legislation in July to establish the agency and open the agency's doors in the second half of 2007.

¶3. (SBU) The agency's opening has been delayed a number of times previously (ref A), and passage of the implementing legislation is far from certain. The Labour-led New Zealand government lacks the votes in Parliament to pass the legislation on its own and has no support yet from any other party. Some opponents are concerned about Australia's possible dominance of the agency, and others are worried that it would mean higher costs for industry and consumers in New Zealand. Proponents say that New Zealand's participation in the joint agency would cost less than if it tried on its own to extend its regulatory authority to devices and other non-drug health products.

Medical devices, complementary medicines

¶4. (SBU) Under the proposed rules, the agency would require licenses for all therapeutic goods and recover all its regulatory costs through fees and charges. That would be particularly burdensome for New Zealand's medical device and complementary medicine sectors,

which have not been required to obtain pre-market approval for their products and pay no licensing or other regulatory fees. While the draft rules provide for a three-year transition period for product licenses to be obtained, industry representatives expect the fees to be so high that they will have to seek cheaper sources -- outside the United States -- for medical devices and complementary medicines. They expect the fees to be similar to those already charged in Australia, which has a population and market roughly five times as large as New Zealand's. They predict the compliance costs would force many smaller distributors and importers out of business in New Zealand.

¶5. (SBU) The draft rules also provide that the agency would conduct all conformity assessments for medical devices, including audits of manufacturers and testing of products to ensure they meet relevant standards, which also would increase the sector's costs. Medical device representatives noted that the proposed agency would accept European certification, but not U.S. Food and Drug Administration certification. As one representative said, that points to the need for a mutual recognition agreement between Australia and the United States, which presumably would enable the joint agency to accept FDA certification.

¶6. (SBU) The industry representatives said they support the agency in principle, recognizing the need for regulation of their products to ensure public safety. However, they were disappointed that their years of consultations with the government about their concerns regarding a new regulatory regime were not reflected in the proposal. They had hoped that the government at least would set fees according to the size of the product's market.

Prescription drugs

¶7. (SBU) On the other hand, the pharmaceutical industry sees the

joint agency as an improvement over New Zealand's existing small and overtaxed regulatory regime, in which obtaining marketing approval for prescription medicines can take more than three years. The agency also could represent a cost-savings by providing a single point of entry for both markets, as opposed to requiring a product license in each country. The industry is concerned, however, about whether labeling rules and other such requirements could be met within three years. It is advocating a five-year transition period.

¶8. (SBU) The drug industry also says it will withdraw support of the agency if the New Zealand government uses it as an excuse to ban direct-to-consumer advertising (DTCA), which some firms have employed to boost sales of unsubsidized medicines in New Zealand's tightly restricted market. Australia allows only disease-based, awareness-building advertising, while New Zealand is the only country in the world besides the United States that allows the pharmaceutical industry to promote its products directly to the public. (The government is reviewing its policy on direct-to-consumer advertising of prescription medicines, in preparation for drafting new legislation on the regulation of DTCA. Such legislation is necessary because the law that would enable New Zealand to participate in the joint agency also would repeal the Medicines Act 1981, which allows DTCA.)

Comment

¶9. (SBU) The joint agency's higher regulatory costs could lead to a decline in sales of U.S. medical devices and other therapeutic products in New Zealand. Failure to recognize FDA certification also would add a discriminatory barrier to U.S. medical devices. While the need for improving regulation of therapeutic products in New Zealand should be acknowledged, post suggests these concerns be raised in the Trade and Investment Framework Agreement talks with New Zealand scheduled for July 27.

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